UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/852,154 | 05/09/2001 | John J. Voorhees | 1718-009B | 3869 |

7590 08/25/2004

BRADLEY N. RUBEN
463 FIRST ST. SUITE 5A
HOBOKEN, NJ 07030-1859

| EXAMINER | |
|---|---|
| KIM, VICKIE Y | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1614 | |

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/852,154 | VOORHEES ET AL. | |
| | Examiner | Art Unit | |
| | Vickie Kim | 1614 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-34 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-34 are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9, 18-19 and 21, drawn to a composition comprising a non-retinoid inhibitor of a dermal matrix-degrading enzyme(e.g. AP-1 inhibitors, NF-kB inhibitors, elastase inhibitors, adhesion antagonists or mixtures thereof); and an active ingredient selected from comedolytics, antibacterials, anti-inflammatories, retinoids, glucocorticoids, and compatible mixtures thereof, classified in class 514, subclass variable based on the species.

It is noted that the claims 18-19 that are directed to a method of claim 1 are improper dependent claims because the claim 1 is composition claim. It is noted that amending claims 18-19 into a method claims will be subject to further restriction requirement. Amending the claims 18-19 with " a composition of claim 1 " would avoid possible further restriction as mentioned.

II. Claims 10-17, drawn to a method of treating acne comprising the steps of: orally administering an active ingredient for the treatment of acne; and topically administering a non-retinoid, non-glucocorticoid inhibitor of a dermal matrix degrading enzyme to acne affected skin, classified in class 514, subclass 859.

III. Claims 20-25, drawn to a combined therapy for alleviating acne scarring, comprising a compatible combination of: a non-retinoid or

antagonist of an receptor sensitive to LPS-like material; and an active ingredient selected from the group consisting of comedolytics, antibacterials, anti-inflammatories, retinoids, glucocorticoids, non-retinoid MMP inhibitors, and compatible mixtures thereof, classified in class 514, subclass variable based on the species.

IV. Claims 26-30, drawn to a method of treating acne comprising the steps of: administering an active ingredient for the treatment of acne and topically administering a non-retinoid, non-glucocorticoid inhibitor or antagonist of a receptor sensitive to LPS0like compounds induced or produced by P. acnes, classified in class 514, subclass 859.

V. Claims 31-32, drawn to a method for treating acne, comprising administering a non-retinoid inhibitor of NF-kB to a patient in need thereof.

VI. Claims 33-34, drawn to a method for treating acne, comprising administering an inhibitor that prevents CD-14 from activating toll-like receptors.

The inventions are distinct, each from the other because of the following reasons:

1. Inventions I and II-VI are related as product and process of use and/or unrelated. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be

practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). Acne treatment could be achieved by materially different product. For example 5-alpha reductase inhibitors(e.g. progesterone, spirono-lactone) are effectively used in acne treatment. In addition to that these inventions may not be related to each other because the composition which the claims 10-17 require could be different from composition of the invention I or II. For instance, invention I requires non-antioxidant mmp inhibitors where invention III requires mmp inhibitors including one having anti-oxidant feature.

2. Inventions II, IV-V or VI; and III are also unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). For instance, the therapeutic agent required for acne treatment can be materially different than that for invention III(i.e. acne scarring treatment).

3. Inventions II, IV-V and V are also patentably distinct because each invention utilizes materially different product wherein the biological function(i.e. underlying mechanism, etc) or biological effects(responses) are also different as evidenced by applicants own claims.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art, the search required for each group is not same, wherein a reference which anticipates the invention of Group I would

not render the invention of Group II or III obvious, absent ancillary art, restriction for examination purposes as indicated is proper.

***Election of Species***

1. Upon the election of patentably distinct invention,applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. For example, claim 1 is generic.

If invention of Group I is elected, applicant is required to elect (a) the inhibitor selected from AP-1 inhibitors, NF-kB inhibitors, elastase inhibitors, adhesion antagonists, and (b) the active ingredients among an antibacterial, MMP inhibitor, neutrophil elastase inhibitor, or antioxidant.

2. Because a combination drug is not obvious over a combination drug containing different materials(species) under USC 103, a combination drug is considered to be a patentably distinct over other combination drug. Furthermore, because each disclosed species does not share chemical similarities nor same physical features or biological functions, the search required for entire combinations are extremely burdensome. The traverse is not accepted, as not all invention/species encompassed by the genus would be classified together.

3. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

**Rejoining practice**

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

***Conclusion***

4. All the pending claims are subject to restriction requirement.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 571-272-0579. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0953. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

VICKIE KIM
PRIMARY EXAMINER

Vickie Kim
Primary Patent Examiner
August 9, 2004
Art unit 1614